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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT PAPER NUMBER
1501 5

DATE MAILED: 12/30/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/678,762

Applicant(s)

Cohn et al.

Examiner

Frederick Krass

Group Art Unit

1501



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-35 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-35 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1501

Frederick Krass

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Indefiniteness Rejection

Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1, third line of the claim, "polymeric composition comprising" is confusing and should read --- polymeric composition comprising polymers which are --- since it is the polymers which are ABA triblock copolymers, not the composition that contains them.

b) The term "substantially non-crosslinked" in claim 1 is a relative term which renders the claim indefinite. The term "substantially non-crosslinked" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that the first paragraph of page 18 of the specification only provides preferred examples of substantially non-crosslinked polymers but does not define the term per se.

c) Claim 3, third line of the claim, "or" should be changed to --- and --- since current Markush group practice requires the use of the latter in conjunction with "selected from the group consisting of".

d) Claim 5, penultimate line, "or" should be changed to --- and --- to comply with current Markush group practice.

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e) Claim 6, second line of the claim, "size" should be changed to --- weight --- since "Da" is a unit of the latter, not the former.

f) Claims 9 and 16, the second line of each claim, "such as" renders same indefinite since it is not clear if the claims are limited only to the preformed structures specifically recited therein.

g) Claim 19, last line, the term poly(ethylene oxide) "rich" is a relative term which renders the claim indefinite. The term "rich" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

h) Claim 24, second line of the claim, the phrase "such as" is indefinite for the reasons discussed above.

i) Claim 26, last line, the term poly(oxyethylene) "rich" is indefinite for the reasons given above.

j) Claim 31, second line, the term "such as" is indefinite for the reasons provided above.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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a) Claims 1-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn et al (USP 4,826,945).

The instant claims recite methods for “reducing or preventing adhesions in a patient comprising exposing tissue which has been subjected to tissue damage and is at risk for the formation of adhesions to a polymeric composition ...” comprising certain ABA block copolymers (emphasis added). Thus, it is the underlined positive process steps which must be present in the prior art for anticipation.

The prior art discloses the instantly claimed ABA block copolymers and exposes same to tissue which has been subjected to damage and is at risk for the formation of adhesions since the copolymers are used to produce drug-containing articles used in surgery such as films, hollow tubes, beads, gels, etc: see column 4, the first paragraph. Thus, the prior art meets each and every claimed limitation and anticipates same, both from the viewpoint of “for reducing or preventing adhesion” being a statement of intended use which carries no weight in determining patentability, and from the viewpoint that since the prior art places the same ABA block copolymers in contact with essentially the same type of tissues (surgically damaged tissues), reduction and/or prevention of adhesions would be reasonably expected to occur inherently therein.

b) Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Casey et al (USP 4,452,973).

The prior art discloses hydroxyl-terminated ABA polylactide block copolymers which can be used in the form of drug-containing beads, gels, etc. to produce articles useful in surgery (column 2, lines 59-63). The rationale for this rejection is the same as that given in subsection a) immediately above.

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Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a) Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheffield et al in view of Cohn et al.

The primary reference teaches the use of polylactide copolymers, in gel form, as carriers for NSAIDs to be used in the inhibition of postsurgical adhesions. The reference does not specify ABA block copolymers.

The secondary reference teaches that applicants' preferred ABA polylactide block copolymers "find advantageous utility in the manufacture of surgical articles and pharmaceutical compositions as is known in the art for polymers, absorbable in living animals" (column 3, lines 65-68). The ABA block copolymers are preferred to conventional polylactide copolymers due to their better biodegradation kinetics (column 3, lines 51 through 56). This rejection will assume, for the sake of argument and completeness of the record, that the reference differs from the instant claims in that it does not specify the reduction and/or prevention of surgical adhesions.

It would have been obvious to have used the instantly claimed ABA polylactide block copolymers as the generally suggested polylactide polymers of the primary reference, motivated by the reasonable expectation that same would provide improved biodegradation kinetics as taught by the secondary reference.

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b) Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheffield et al in view of Casey et al.

The primary and secondary references have been discussed above. It would have been obvious to used the ABA polylactide block copolymers of the secondary reference as the generally suggested polylactide polymers of the primary reference, motivated by the reasonable expectation that same are known for surgical applications as taught by the former.

Any inquiry concerning this communication should be directed to Frederick Krass at telephone number (703) 308-2351. The examiner is generally available Monday through Friday during the core hours of 9:30 a.m. through 3:00 p.m. If not available, use of the examiner's voice mail is encouraged; a direct fax number for Group Art Unit 1501 is also available at (703) 305-5246.

Frederick Krass
Primary Examiner
Group Art Unit 1501

